

BANOPHEN - diphenhydramine hcl capsule

Unit Dose Services

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Banophen

Active Ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 50 mg

Purpose

Antihistamine

Use

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat and nose
- Temporarily relieves these symptoms due to the common cold
 - runny nose
 - sneezing

WARNINGS

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist

before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	Take 1 capsule (50 mg)
children under 12 years of age	ask a doctor, the proper dosage strength is not available in this package**

**Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

Other Information

- Store at room temperature, USP.
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- Protect from moisture
- Contains lactose

Inactive Ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

Questions?

Questions or comments? (800) 616-2471

Distributed by

MAJOR® PHARMACEUTICALS
 17177 N Laurel Park Drive, Suite 233,
 Livonia, MI 48152

HOW SUPPLIED

Product: 50436-3762

NDC: 50436-3762-1 30 CAPSULE in a BOTTLE

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE BANOPHEN (DIPHENHYDRAMINE HYDROCHLORIDE) CAPSULE

BANOPHEN™
Diphenhydramine HCL
Dist by: Major Pharmaceuticals, Livonia, MI 48150

NDC: 50436-3762-1 50 MG / 30 CAP
Pkg by: Unit Dose Services, LLC
Danis, FL 33004

ANTHISTAMINE	Complete Allergy Medication	When using this product: * Marked drowsiness may occur * Avoid alcoholic drinks * Alcohol, sedatives and tranquilizers may increase drowsiness * Use caution when driving a motor vehicle or operating machinery * Excitability may occur, especially in children
For the temporary relief from symptoms of: * Upper Respiratory Allergies * Hay Fever Each Capsule Individually Banded For Your Protection		
Drug Facts:		* If PREGNANT OR BREAST FEEDING, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Active ingredient (in each capsule) Diphenhydramine Hydrochloride 50 mg	Purpose Antihistamine	
Uses: Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold * Sneezing * Runny nose * Itchy, watery eyes * Itchy throat and nose		Inactive Ingredients: D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.
Warnings: Do not use * With any other products containing diphenhydramine including one applied topically		
Ask a doctor before use if you have* Glaucoma * A breathing problem such as emphysema or chronic bronchitis * Difficulty in urination due to enlargement of the prostate gland		 <p>LOT # XXXXXX EXP: XXXXXX MFG NDC: 0904-5307-80 MFG LOT # XXXXXX</p>
Store at room temperature, USP ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE TAKING SEDATIVES OR TRANQUILIZERS		

Directions:
*Adults and children 12 years and older: Take 1 capsule (50mg) every 4 to 6 hours, not to exceed 6 capsules in 24 hours
*Children under 12 years of age: Ask a doctor, the proper dosage strength is not available in this package**
** Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package. Other Information:
Do not use if either capsule band or imprinted safety seal under cap is broken or missing * Protect from excessive moisture
*Use by expiration date on package * Contains lactose

NDC: 50436-3762-1 50mg / 30 Cap
Banophen™ (Diphenhydramine HCL)
Lot # XXXXXX Exp: XXXXXX

NDC: 50436-3762-1 50mg / 30 Cap
Banophen™ (Diphenhydramine HCL)
Lot # XXXXXX Exp: XXXXXX

BANOPHEN

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-3762(NDC:0904-5307)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (banded red around the middle)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC;836
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-3762-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	11/02/2009	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-3762) , RELABEL(50436-3762)

Revised: 11/2017

Unit Dose Services